

Changes to legislation: There are currently no known outstanding effects for the Human Fertilisation and Embryology Act 1990, Paragraph 11C. (See end of Document for details)

SCHEDULES

[^{F1}SCHEDULE 3A

SUPPLEMENTARY LICENCE CONDITIONS: HUMAN APPLICATION

Textual Amendments

- F1** Sch. 3A inserted (25.5.2007 for certain purposes, otherwise 5.7.2007) by [The Human Fertilisation and Embryology \(Quality and Safety\) Regulations 2007 \(S.I. 2007/1522\)](#), regs 1, **30**

[^{F2}Modifications to the first, second and third Directives

Textual Amendments

- F2** Sch. 3A paras. 11A-11C and cross-heading inserted (31.12.2020) by [The Human Fertilisation and Embryology \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/482\)](#), regs. 1, **2(17)(c)** (with reg. 4) (as amended by [The Human Fertilisation and Embryology \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1307\)](#), regs. 1, **16(c)**); 2020 c. 1, Sch. 5 para. 1(1)

- 11C (1) The modifications to the third Directive are as follows.
- (2) Annex 1 is to be read as if—
- (a) in paragraph A.1—
 - (i) for “responsible person” there were substituted “ person responsible ”;
 - (ii) for “as provided in Article 17 of Directive [2004/23/EC](#)” there were substituted “ in accordance with the requirements of sections 16 and 17 of the Human Fertilisation and Embryology Act 1990 ”;
 - (b) in paragraph A.4, for “laid down in this Directive” there were substituted “ required by the Human Fertilisation and Embryology Act 1990 ”;
 - (c) in paragraph C.6, for the words from “requirements of Council” to the end there were substituted “ requirements of the Medical Devices Regulations 2002 ”;
 - (d) in paragraph D.1, for “laid down in this Directive” there were substituted “ required by the Human Fertilisation and Embryology Act 1990 ”;
 - (e) in paragraph E.1, for “laid down in this Directive” there were substituted “ required by the Human Fertilisation and Embryology Act 1990 ”;
 - (f) in paragraph E.8, the reference to the competent authority were a reference to the Authority.
- (3) Annex 2 is to be read as if—
- (a) in the first paragraph, the reference to the competent authority were a reference to the Authority;

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- (b) in paragraph A, for the words from “the tissues and cells must” to the end there were substituted “tissue establishment procedures must ensure that the licence conditions in paragraph 9 of Schedule 3A to the Human Fertilisation and Embryology Act 1990 are met”;
- (c) in paragraph B.3, for the words from “the standards” to the end there were substituted “the requirements of paragraph 10 of Schedule 3A to the Human Fertilisation and Embryology Act 1990”;
- (d) in paragraph B.8, the second sentence were omitted;
- (e) in paragraph C.2, for “laid down in this Directive” there were substituted “of Schedule 3A to the Human Fertilisation and Embryology Act 1990”;
- (f) in paragraphs C.4 and C.5, any reference to the responsible person as defined or specified in Article 17 of Directive [2004/23/EC](#) were a reference to the person responsible in accordance with section 17 of this Act;
- (g) in paragraph D.5, the reference to the competent authority were a reference to the Authority;
- (h) in paragraph E.2(h), for “as set out in Articles 5 to 6” there were substituted “in accordance with paragraph 3 of Schedule 3A to the Human Fertilisation and Embryology Act 1990”.[]

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